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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,229	04/08/2004	Tara Ziolo	5490E-000365	9402

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,229

Applicant(s)

ZIOLO ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardo et al. (US Pub. 2004/0127896 A1) in view of Konieczynski et al. (US Pub. 2004/0127899 A1).

Lombardo et al. disclose a bone fixation apparatus comprising a bone fixation plate (Fig. 1 below) having a fixation hole (Fig. 1 below) and a modular bone fixation fastener received in the fixation hole, the bone fixation fastener including a shaft member (Fig. 1 below) and a head member (Fig. 1, ref. 18), the shaft member having an outer cam at a first end (Fig. 21), the outer cam capable of mating with a corresponding inner cam (Fig. 7A, all refs. 31) of the head member. The outer cam and the inner cam each have at least one lobe (Fig. 21 below) (Fig. 7A, ref. 31). The outer cam and the inner cam each have a plurality of lobes (Fig. 21 below) (Fig. 7A, ref. 31). The fixation hole includes a countersunk portion receiving at least a portion of the head member of the bone fixation fastener (Fig. 1 below). Each of the outer and inner cams includes three equidistant lobes (Fig. 21 below) (Fig. 7A, ref. 31). Fig. 7A shows the inner cam as having more than three equidistant lobes, but three lobes are also possible (paragraph 0010, lines 3-7)). The inner surface of the fixation hole is spherical

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and engages a spherical outer surface of the head member (Fig. 1 below). The definition of spherical, according to the Merriam-Webster Online Dictionary, is "relating to or dealing with a sphere or its properties". The holes and outer surface of the head member relate to a sphere's properties, since they both have some of the features of a sphere. They are both circular and have radii. The fixation fastener is capable of being positioned at a plurality of angles relative to the plate before locking (paragraph 0004, the final sentence). Furthermore, one could position the fastener at virtually any angle before locking the pieces together, since nothing is connected yet (it is not locked). The bone fixation plate includes a viewing window (Fig. 2 below). The bone fixation plate is a spinal fixation plate capable of securing first and second vertebral bodies relative to one another (paragraph 0002, lines 7-12). The bone fixation plate is a spinal fixation plate capable of securing at least three vertebral bodies relative to one another. With the plate's three sections (Fig. 1) it is capable of being placed over and capable of securing at least three vertebrae. The bone fixation apparatus comprises at least one aperture receiving an anchoring fastener (Fig. 2 below). The bone fixation apparatus comprises at least another fixation hole receiving another modular fixation fastener (Fig. 1 below). Lombardo discloses a bone fixation apparatus in combination with an insertion and removal tool, the tool comprising a first driver attached to a handle, the driver capable of engaging the head member for rotation of the head member relative to the shaft member (Fig. 8A below). The tool comprises a second driver adapted to engage the shaft member for inserting and removing the shaft member to and from a bone portion when the fixation member is not locked (Fig. 8A below). Removing the interchangeable

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head on the drill bit receiving channel 45 would reveal a second driver that is capable of inserting and removing the shaft member. The head of the screw could be drilled in directly if the size of the drill bit receiving channel is the right size; if it is the incorrect size the drill bit receiving channel could bore a hole directly in the bone of the patient, and then the drill bit receiving channel could engage the head of the shaft member and push the shaft member into the pre-made hole, and knock the shaft member out of the hole if the shaft member is struck with the drill bit receiving member. Lombardo et al. further disclose a bone fixation apparatus comprising a bone fixation plate (Fig. 1 below) having a fixation hole and a modular bone fixation fastener received in the fixation hole (Fig. 1 below), the bone fixation fastener comprising a shaft member having a head-receiving first end (Fig. 21 below), the first end including a multi-radius outer surface defining a cam lobe (Fig. 21 below) and a head (Fig. 7A, ref. 18) having a multi-radius inner surface defining a cam lobe (Fig. 7A, ref. 31) capable of mating with the shaft cam lobe. The inner head surface and the outer shaft surface each define a plurality of cam lobes (Figs. 21 below) (Fig. 7A, ref. 31), which are capable of mating. The inner surface of the fixation hole is spherical and is capable of engaging a spherical outer surface of the head members (Fig. 1 below). The head member can be placed in the hole, and the outer surface of the head member can be placed in contact with the inner surface of the fixation hole. The fixation fastener is capable of being positioned at a plurality of angles relative to the fixation plate when the head member is not expanded. When the head member is not expanded, then the plate is not "locked" to the screw. This allows the fixation fastener to be placed at any angle with respect to the screw. Lombardo further

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discloses a bone fixation apparatus comprising a bone fixation plate having a fixation hole (Fig. 1 below), the fixation hole having a first diameter in a plane generally parallel to an upper surface of the bone fixation plate (Fig. 1 below), and a modular bone fixation fastener received in the fixation hole (Fig. 1 below), the bone fixation fastener including a shaft member (Fig. 21 below) defining a shaft axis and a head member (Fig. 7A, ref. 18) capable of being carried by the shaft member, the head member capable of rotating about the shaft axis relative to the shaft member between a first position and a second position. The head member can rotate around the shaft member between at least two positions, the locked position and the unlocked position. The head member has a generally spherical outer surface (Fig. 7A). The fixation hole is generally spherical (Fig. 1 below). The shaft member has a cam capable of mating with a corresponding cam of the head member (Figs. 21 below).

Lombardo discloses a bone fixation apparatus comprising: a bone fixation plate (Fig. 1 below) having a fixation hole (Fig. 1 below); and a modular bone fixation fastener received in the fixation hole, the bone fixation fastener including a shaft member (Fig. 1 below) and a head member (Fig. 7A, ref. 18), the shaft member having an outer cam (Fig. 21 below) at a first end, the outer cam defined by a curve of variable radius (since the lobes create different radii), the head member having an inner cam (Fig. 7A, all refs. 31) defined by a curve of variable radius (since the lobes create different radii), each of the curves of the outer and inner cams being devoid of discontinuities (since the internal surface of the outer cam and the outside periphery of the inner cam can be unbroken, as in Fig. 7A, ref. 18) and kinks and the outer cam of the shaft member is

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capable of mating with the inner cam of the head member. The definition of "kink" according to the Merriam-Webster Online Dictionary is "a short tight twist or curl caused by doubling or winding of something upon itself". Nowhere is the device doubling or winding upon itself, therefore the device can be considered to be devoid of kinks. Each of the outer and inner cams includes a plurality of equidistant lobes (Fig. 21 below) (Fig. 7A, ref. 31). The inner surface of the fixation hole is spherical (Fig. 1 below) and engages a spherical outer surface of the head member (Fig. 2, below), such that the fixation fastener is capable of being positioned at a plurality of angles relative to the plate before locking.

Lombardo does not disclose the head member being expandable.

Konieczynski et al. disclose a head member that is expandable (Fig. 1A below), in order to allow the head member to lock the bone plate to the bone screws (paragraph 0073, lines 1-4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the head member of Lombardo et al. out of an expandable material as taught by Konieczynski et al, in order to lock the screw to the plate (paragraph 0089, lines 1-3).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Lombardo et al. in view of Konieczynski et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the

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reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The device of Lombardo in view of Konieczynski et al. is inherently capable of performing a method for fastening bone portions to each other, the method comprising: aligning a fixation plate for attachment to the bone portions; aligning a first cam defined in a first portion of a modular fastener relative to a second mating cam defined in a second portion of the fastener, each of the first and second cams defined by a continuous curve of variable radius and continuous slope; inserting the modular fastener to one of the bone portions through a corresponding hole in the fixation plate; and radially expanding a portion of the fastener relative to the hole, to prevent back out of the fastener; selecting the orientation of the fastener relative to the fixation plate; rotating the first cam out of alignment relative to the second cam; pressure-locking the fastener to the fixation plate and thereby preventing relative movement between the fixation fastener and the plate; rotating a head member of the modular fastener relative to a shaft of the fastener to expand the head member; rotating the head member to establish a first expanded diameter of the head member; and rotating the head member to establish a second expanded diameter of the head member.

The device of Lombardo in view of Konieczynski et al. is inherently capable of performing a method of surgically repairing bone with a fixation plate having a plurality of fixation holes, the method comprising : cam-aligning a first cam of an expandable head member of a modular fastener to a mating second cam of a shaft member of the modular fastener, each of the first and second cams defined by a continuous curve of variable radius and continuous slope; inserting the fastener in one of the fixation holes; and radially expanding the head member to prevent back out of the fastener from the fixation hole; radially expanding comprises pressure locking the head member against the fixation hole and thereby preventing relative movement between the fixation fastener and the plate; expanding further comprises rotating the head member out of cam alignment relative to the shaft member; rotating includes engaging a portion of the head member with a driver and rotating the driver; unlocking the fixation fastener; wherein unlocking comprises unexpanding the head member ; removing the fixation fastener; unexpanding comprises rotating the head member into cam alignment with the shaft member; rotating the head member to establish a first expanded diameter of the head member; and rotating the head member to establish a second expanded diameter of the head member.

Response to Arguments

Applicant's arguments filed 09/20/2006 have been fully considered but they are not persuasive.

Regarding applicant's argument that the Konieczynski et al. reference cannot be combined with the Lombardo et al. reference to provide an expandable head member,

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the examiner respectfully disagrees. Applicant argues that the head members of Lombardo et al. are structured to engage with the head of their respective fasteners in particular ways and cannot be replaced by other washers without destroying the structure and function of the implant of Lombardo et al. The structure of the device would naturally change, since it is being modified by a secondary reference, but that does not mean that the structure will be destroyed. As for the function of the device, the device of Lombardo et al. is used as a bone plate to fuse anatomical structures together (abstract, lines 10-12). If modified by Konieczynski et al., the device would retain its ability to function as a bone plate to fuse anatomical structures together.

Regarding applicant's argument that Lombardo et al. fails to disclose a shaft with an outer cam/shaft cam/first cam that is defined by a continuous curve of continuous slope and variable radius, the examiner respectfully disagrees. The outer cam/shaft cam/first cam of Lombardo et al. (Fig. 21 below) is defined by a continuous curve, since the outer periphery of the cam is continuous (i.e. there are no gaps). The outer cam/shaft cam/first cam exhibits a continuous curve. The definition of curve, according to the Merriam-Webster Online Dictionary is "a line especially when curved." The entire periphery of the cam is formed by at least a line at all points, therefore the entire periphery is curved. The radius of the cam varies since the lobes protrude along the periphery of the cam. Applicant further argues that the inner cam (Fig. 7A, ref. 18) is not defined by a continuous curve of continuous slope and variable radius. The inner cam (Fig. 7A, ref. 18) is defined by a continuous curve of continuous slope and variable radius for the same reasons that the outer cam has these properties.

Applicant argues that the device of Konieczynski et al. in view of Lombardo et al. would fail to provide elements of discontinuous wedges and tangs mating with track portions defined in splays of the washer. The head member of Lombardo et al. is merely being modified by the head member of Konieczynski et al. to become expandable. The discontinuous wedges and tangs mating with track portions defined in splays of the washer are not needed in the modification of the head member of Lombardo et al. Furthermore, the limitations on which the Applicant relies (i.e., wedges, tangs, track portions and splays) are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.

With regards to applicant's argument that Lombardo et al. fails to disclose an expandable head member that in a first position has a maximum diameter that is smaller than a first diameter of the fixation hole, and in the second position the expandable head member has a maximum diameter that is greater than the first diameter, the examiner agrees. Lombardo et al. alone fails to disclose an expandable head member, however Lombardo et al. in view of Konieczynski et al. does disclose an expandable head member, as stated in the above rejection under U.S.C 103(a). The expandable head of Lombardo et al. in view of Konieczynski et al. is capable of being in a first position where the maximum diameter of the expandable head member is smaller than a first diameter (Fig. 3B, the diameter near the top of the plate, above the grooves of ref. 30) of the fixation hole, as seen in Fig. 28 of Lombardo et al. In Fig. 28, the head is already rotatably mounted to the shaft (paragraph 0078, lines 2-4). This indicates that the diameter of the head is smaller than a first diameter of the fixation hole, so that the

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preassembled head can still be placed into the fixation hole (paragraph 0078, lines 5-11). Once the preassembled head is placed into the fixation hole, the cams can be forced to engage each other by turning them relative to each other so that the lobes engage each other and a force is applied (paragraph 0078, lines 5-11). The expandable head of Lombardo et al. in view of Konieczynski et al. could then be expanded and forced to move into the groove of Fig. 3b, ref. 30. This can be considered to be the second position of the expandable head member, and the diameter of the head member would then be larger than the first diameter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

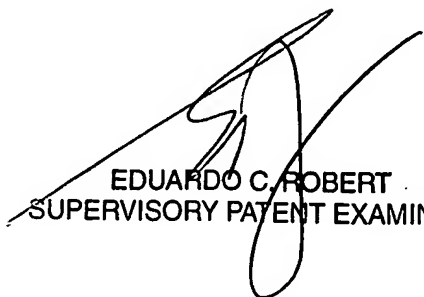
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

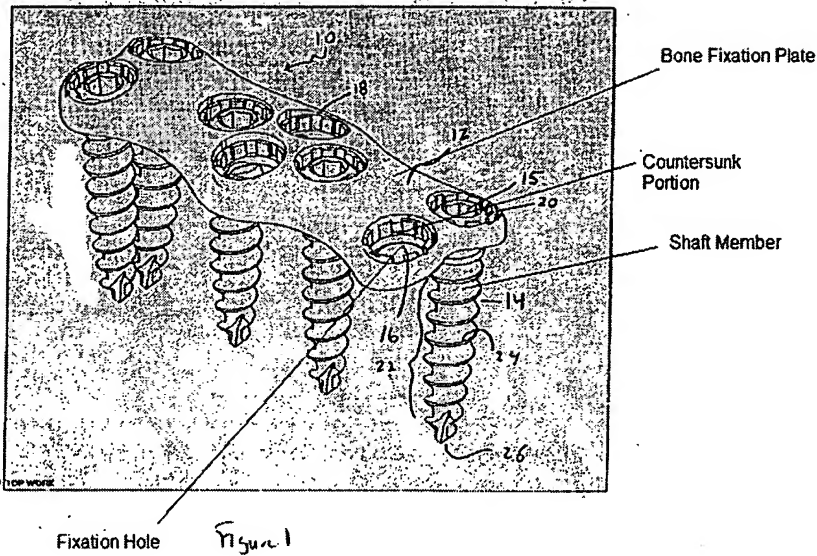
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

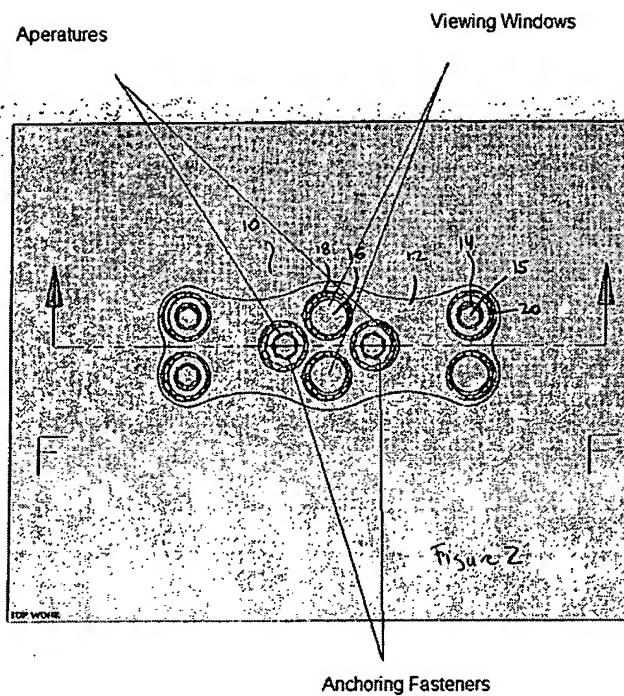
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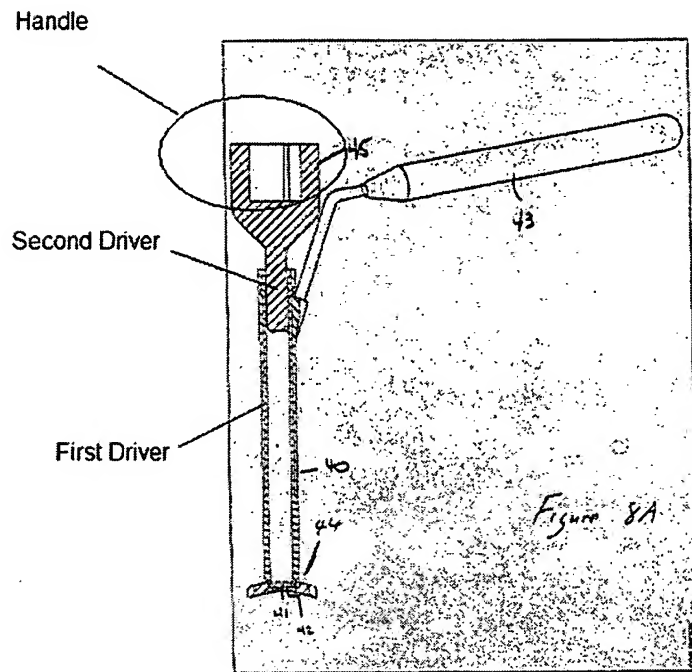


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER



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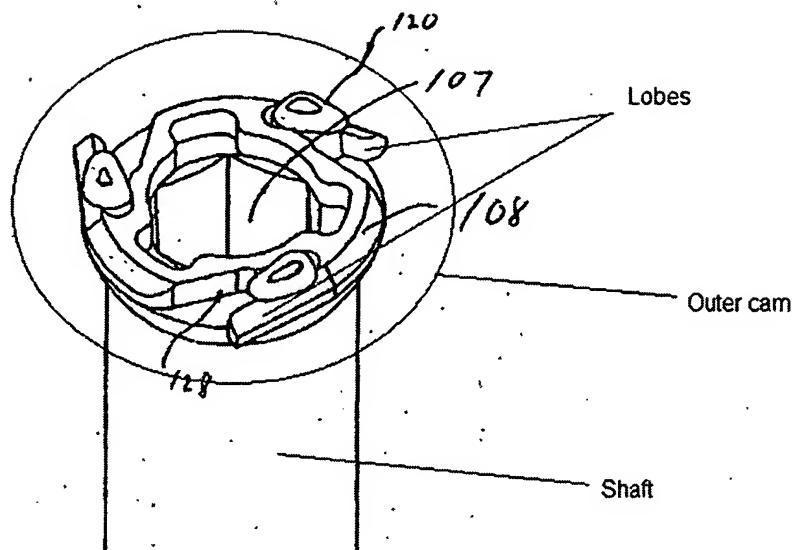


Figure 21

